July 27, 2009

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-D-0260; Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007; Availability; Announcement of Further Delay in Implementation of the Food and Drug Administration Amendments Act of 2007

Dear Sir/Madam:

Now celebrating its Centennial year, the American Feed Industry Association (AFIA) is the world's largest organization devoted exclusively to representing the business, legislative and regulatory interests of the U.S. animal feed industry and its suppliers. AFIA also is the recognized leader on international industry developments. Members include more than 500 domestic and international companies and state, regional and national associations. Member-companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and companies which supply other products, services and supplies to feed manufacturers.

The feed industry makes a major contribution to food safety, nutrition and the environment, and it plays a critical role in the production of healthy, wholesome meat, milk, fish and eggs. More than 75 percent of the commercial feed in the United States is manufactured by AFIA members.

Feed, ingredient and pet food manufacturers are subject to the Food and Drug Administration Amendments Act of 2007 and comments are presented here to address the feed industry's concerns.

Introduction

AFIA applauds FDA for its efforts to implement this act in a reasonable fashion by offering this set of questions and answers. However, a major concern is that final guidance be issued with sufficient lead time for industry to make needed operating changes by the effective date of September 8. AFIA recommends some reasonable time (e.g. 30-60 days) after release of the final guidance to allow firms to assimilate this guidance into standard operating procedures.

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From the feed industry perspective, AFIA is concerned that much of the draft guide focuses more on human food than animal food or feed and believes some of the examples presented are not appropriate and need amending. Specific instances and suggestions appear below by question. One major deficiency of the draft guide is the lack of specific examples of a "reportable food" and similarly, a list of specific examples that are not "reportable foods" from the feed industry perspective. These should be added to provide insight into what FDA expects to be reported and not reported, thereby limiting the potential for excessive reporting.

Another major concern of AFIA is FDA's ability to maintain confidentiality of the data it reviews and collects via the electronic portal. AFIA is particularly concerned that FDA maintain the confidentiality of a facility's quality control description, including but not limited to laboratory methods and laboratories utilized, customer and supplier lists and brand named equipment used at the facility. FDA should train and strictly require adherence to a policy that would limit the possible release of such information in accord with the applicable Freedom of Information Act and rules. Our experience is that a substantial amount of proprietary information is not always redacted from FDA's establishment inspection report (EIR), a conclusion that is supported by at least one General Accountability Office report.

Although FDA officials have addressed this issue at the first public meeting on the Reportable Food Registry electronic portal, AFIA is also concerned regarding the entities or persons who will have access to these reportable food records. If a state official reports a reportable food to the FDA, will the company producing that food have access to that record to determine what is and is not factual and be able to amend that record? FDA should describe how this access will be controlled in the guidance.

Similarly, will FDA communicate with a firm holding the reportable food to ensure that any information the agency releases is accurate and does not compromise the confidential information of the firm regarding its products?

Specific Question Concerns

Question 12. This question which addresses a pathogen discovered in testing appears to focus more on the testing and retesting issue than on the finding of a pathogen and the reportability of that finding. However from the animal food industry perspective, the mere finding of a pathogen does not automatically make the product a reportable food. AFIA suggests amending the question to say the following: "I received a positive microbiological test result indicating the presence of a pathogen in food and based on this test result I have determined that the product from which this sample was taken may have the potential of being a reportable food due to the nature of the pathogen, level discovered and scientific evidence. However,…"

The change would avoid the implication that finding of a pathogen is an automatic determination of a reportable food. Many factors make that "leap" possible, but these factors are not discussed here. AFIA understands that the primary thrust of this question is to discourage "testing into compliance" and agrees with that approach, but the clarification we suggest would assist in removing a faulty assumption.

Questions 23 and 24. These questions address responsible parties reporting reportable food occurrences up and down the supply chain. Although this may be appropriate for human food, in the feed industry, many products utilized for feed going into ingredient facilities may not be suitable for use in feed until further processed, such as co-products coming from meat packing plants (e.g. meat scraps or fats), mined minerals (e.g. copper or zinc compounds). Therefore, determination that raw materials are "reportable foods" may not be appropriate. In fact, many of these raw materials that are made into safe feed ingredients are further diluted by manufacture at other locations (i.e. feed mills) into finished feed. FDA should amend the questions to address these issues regarding the reporting of an apparent "reportable food" destined to a further processor that will, in fact, alter the animal food in such as way that it is no longer a reportable food.

Question 28. AFIA does not agree with FDA on the issue of notifying the FDA district office. AFIA believes FDA should exercise that function, so as to not result in duplicative operations by the district office and the agency's headquarters. Firms in a crisis neither want to, nor need to be answering questions from two different parts of the agency.

Summary

AFIA applauds the agency for attempting to describe the requirements of the electronic portal of the Reportable Food Registry. However, we are very concerned that FDA's issuance of a final guidance will not result in adequate time for firms to fully address this new requirement by September 8 and strongly suggest an implementation phase-in *following* the issuance of the final guidance.

Several of the questions are confusing in addressing important issues and need amending to clarify the issues. Hopefully, these will be addressed at future public meeting as well.

AFIA appreciates the opportunity to offer these suggestions and the agency's consideration.

Sincerely,

Richard Sellers
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American Feed Industry Association
Arlington, VA